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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Finnegan, Henderson, Farabow
Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, DC 20005-3315

EXAMINER

CROUCH, DEBORAH

ART UNIT PAPER NUMBER

I632

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/658,862	Applicant(s) STOCKMAN CAMPBELL ET AL.	
	Examiner Deborah Crouch, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-64, 87 and 88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-64, 87 and 88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/803,165.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1632

Applicant's arguments filed May 7, 2004 have been fully considered but they are not persuasive. The amendment has been entered. Claims 61-64, 87 and 88 are pending.

Applicant's amendment to the claims has overcome the obviousness-type double patenting rejection made over U.S. Application Serial No. 09/225,233.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 61-64, 87 and 88 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-16 of U.S. Patent No. 6,525,243 B1 for reasons presented in the office action mailed November 26, 2003.

Claims 61-64, 87 and 88 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 13-21 of U.S. Patent No. 6,147,276 for reasons presented in the office action mailed November 26, 2004.

Claims 61-64, 87 and 88 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11-18 of U.S. Patent No. 6,252,133 B1 for reasons set forth in the office action mailed May 9, 2003.

Applicant agreed to file a terminal disclaimer to U.S. Patent Nos. 6,525,243 B1, 6,147,276 and 6,252,133 B1 once allowable subject matter is identified.

Art Unit: 1632

35 U.S.C. 101 reads as follows :

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 61-64, 87 and 88 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter for reasons presented in the office action mailed November 26, 2003. Claims 61-64, 87 and 88, as written, do not sufficiently distinguish over nonhuman mammals, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. Thus, the claims lack evidence of the hand-of-man. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty* 447 U.S. 303, 206 USPQ 193 (1980). See MPEP 2105.

Applicant argues the claims are to "clones" of a pre-existing, parental mammal, and as such are produced asexually. Nature, applicant argues, does not make clones. The asexual production of clones, applicant states, indicates the "hand of man." These arguments are not persuasive.

The mammals claimed, while admittedly produced by new method, and that the method is asexual, the methods do not alter the mammals from its brethren in the wild or in commerce. There is nothing different about the mammals that provides it with any distinctive quality, characteristic or use over those mammals produced sexually. A comparison would be the production of a calf by embryonic cell nuclear transfer. A calf so produced, as an example, has been produced by the hand of man but nothing about the calf is distinctive over other calves. A calf produced by ECNT would also be considered nonstatutory. This would be true even though the calf would not have a genotype of a prior existing bovine as do the claimed clones. However, the fact that clones have the genotype

Art Unit: 1632

of a prior existing bovine adds to the nonstatutory arguments. The claimed clones, as applicant argues later in their response, are replicas of a known mammal. If the mammals are copies of a previously known mammal that would have been considered nonstatutory, then the copy, the clone, of the mammal cannot be considered statutory. With the presently claimed clones, the ingenuity is with the method, and not the product.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 87 and 88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 87 and 88 contain the term "parental," but the specification does not support such a term. There is no disclosure in the specification that would have conveyed to the skilled artisan at the time of filing that applicant had possession of the term "parental."

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant should consider deleting term "parental" or pointing to support in the specification.

Art Unit: 1632

Claims 61-64, 87 and 88 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nonprimate mammalian clone and a nonembryonic, nonprimate mammalian clone, does not reasonably provide enablement for nonhuman mammalian clones or nonembryonic, nonhuman mammalian clones. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At the time of filing, the skilled artisan would have regarded the cloned primates as unpredictable.

Pennisi cites several scientists working in the area of mammalian cloning who point to a lack of general and reproducible success, thus, emphasizing the lack of predictability at the time of filing. Robert Wall of the USDA is quoted as stating that despite years of effort, "[w]e're in the same bind that we've always been in. A majority of [would be clones] do not make it to term." (Pennisi and Vogel (2000), page 1722, col. 1, parag. 2, lines 9-14). Pennisi and Vogel state that "even when an embryo does successfully implant in the womb, pregnancies often end in miscarriages" (Pennisi and Vogel (2000), page 1722, col. 1, parag. 3, lines 16-18). As the authors state, establishing pregnancies is only part of the problem and is not a guarantee of a cloned mammal being produced (Pennisi and Vogel (2000), page 1726, col. 2, lines 9-11). Thus, at the time of filing, there appears to be such unpredictability that only the cloning of nonprimate mammals was predictable. With particular regards to primates two cloned monkeys were produced, but there have been no subsequent successes in primate cloning (Pennisi and Vogel (2000), page 1726, col. 2, line 6 to col. 3, line 3). In this regard, is a post-filing report in 2002 that the cloning of monkeys, a primate, by nuclear transfer had been successful when embryonic cells were the nuclear donor, not when somatic cells were used as nuclear donor (Mitalipov, abstract).

Art Unit: 1632

Fourteen somatic cell NT embryos were transferred to 3 recipients (Mitalipov, page 1371, col. 1, parag. 1, lines 5-7). Mitalipov states that nuclear reprogramming is a limiting parameter in monkey somatic cell cloning (page 1371, col. 1, parag. 2, lines 13-25). Mitalipov further states, clearly, that somatic cell cloning has not been accomplished in primates (Mitalipov, page 1367, col. 2, parag. 3, lines 1-3). Thus, the art at the time of filing clearly indicates that full breadth of the claimed invention was not enabled. Thus, the skilled artisan would have needed to conduct an undue amount of experimentation without a predictable degree of success to implement the claimed invention for its entire breadth.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 87 and 88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 87 and 88 contain the term "parental." However, parent means "one that begets or brings forth offspring," "an animal or plant that is regarded in relation to its offspring," and "material or source from which something is derived." Thus, the term is confusing as to whether the parent is the nuclear donor or the surrogate mother.

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skills in the art to which said subject matter pertains. patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1632

Claims 61-64, 87 and 88 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated, for reasons set forth in the office action mailed November 26, 2003, by or in the alternative, are rejected over U.S. Patent 5,057,420 issued October 15, 1991 (Massey).

Massey teaches bovine embryos isolated from cows that have been artificially inseminated (col. 3, lines 18-31). Bovines encompassed by the present claims, where claims 61-64 are made by a particular process of the claims, do not have a property that distinguishes them from those bovine embryos and bovines taught by Massey. Producing the claimed clones by nuclear transfer of a nucleus from a differentiated cell isolated from a non-embryonic mammal does not provide a distinguishing feature to the cloned bovines, which would include bovine embryos, bovine fetuses or born-bovines.

In the alternative the bovine embryos and bovines taught by Massey render the claimed clones obvious because there is no disclosed or discernable patentable distinction between Massey's bovines the claimed clones.

The claims require that the clone be of a pre-existing non-embryonic mammal. Massey teaches a pre-existing non-embryonic mammal. A clone is a duplicate of the pre-existing mammal. There is no evidence of record to distinguish the clone from the pre-existing mammal.

Claims 61-64, 87 and 88 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated, for reason set forth in the office action mailed November 26, 2003, by or, in the alternative, are rejected over The Science of Providing Milk for Man, Campbell and Marshall, McGraw Hill Book Co., New York, 1975, pages 48, 49, and 51-56.

At pages 48,49 and 51-56, Campbell and Marshall teach several different bovines that existed prior to applicant's invention. A bovine produced by the claimed methods would not be patentably distinct from any one of the bovines of Campbell and Marshall as the

Art Unit: 1632

method of producing does not provide a patentably distinguishing feature to the claimed mammal.

In the alternative the bovines taught by Campbell and Marshall render the claimed bovines obvious because there is no disclosed or discernable patentable distinction between Campbell and Marshall's bovines and those claimed.

The claims require that the clone be of a pre-existing non-embryonic mammal. Campbell and Marshall teach a pre-existing non-embryonic mammal. A clone is a duplicate of the pre-existing mammal. There is no evidence of record to distinguish the clone from the pre-existing mammal.

Claims 61-64, 87 and 88 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated, for reasons presented in the office action mailed November 26, 2003, by or, in the alternative, are rejected over Sims et al. (1993) Proceed. Natl. Acad. Sci. 90, 6143-6147.

Sims teaches the production of bovines and bovine embryos by nuclear transfer, where the donor nucleus is from a bovine cultured inner cell mass cell (page 6145, col. 2, parag. 2, lines 1-7 and page 6146, col. 1, parag. 2, lines 6-11). The source of the donor nucleus, be it bovine inner cell mass cell or a non-embryonic differentiated cell as claimed, does not provide a patentable distinction on the resulting bovine embryo or bovine. The source of the donor nucleus does not alter the bovine embryo or bovine such that the bovine embryo or bovine encompassed by applicant's claims is patentable distinct from those of Sims et al.

In the alternative the bovine embryos and bovines taught by Sims render the claimed bovine embryos and bovines obvious because there is no disclosed or discernable patentable distinction between Sims's bovine embryos and bovines and those claimed.

Art Unit: 1632

The claims require that the clone be of a pre-existing non-embryonic mammal. Sims teaches a pre-existing non-embryonic mammal. A clone is a duplicate of the pre-existing mammal. There is no evidence of record to distinguish the clone from the pre-existing mammal.

Applicant argues that the relative age between the clone and the parent of the clone does provide a new property/phenotype that makes the clone distinct from the prior existing mammal. Applicant argues that their clone is a time-delayed copy of its parent. Applicant argues that the time-delay is a unique feature in the resultant mammal that is provided by the process. Applicant argues that claims 61-64, 87 and 88 recite "a clone" and is a structural limitation to the claimed invention. Applicant argues that the term "clone" does not make claim 87 and 88 a "product-by-process" claim.

Applicant argues that according to the American Heritage College Dictionary (third edition), "phenotype" is the "observable physical or biochemical traits of an organism, as determined by both genetics and environment." Applicant argues that "age" falls within both of these definitions of a phenotype since it is part of "the appearance" and "the observable physical traits" of a mammal. Applicant argues that a three-year old mammal would appear older than a newborn mammal.

Applicant argues that their process generates features in the resultant mammals that cannot be found in the prior art mammals. "Clones" are copies of a pre-existing mammal, meaning, excluding the parental mammal, they are genetically unlike any other mammal that previously existed. Second, "clones" are a time-delayed copy of the parental mammal. Applicant argues that these features assure that applicant's cloned mammals are distinct and nonobvious from any mammal that previously existed including the parental mammal.

Applicant argues that the combination of being a time-delayed copy of a pre-existing mammal gives the clones unexpected properties. The clone has the same chromosomes as

Art Unit: 1632

a single parent. Since mammals reproduce sexually, this cannot be an expected property of any other mammal. Applicant argues that the clone is younger than its parent and exists during a different time period than its parent. Applicant argues that the unexpected property is that the clone has the same set of chromosomes, but is younger.

These arguments are not persuasive.

Applicant has not established that age is a phenotype. The definition of phenotype as "observable physical or biochemical traits of an organism, as determined by both genetics and environment" is not seen as including "age." First, genetics and the environment do not determine age. Age is a measure of how long, as related to the present rejection, the mammal has been born. Neither genetics nor environment determine how long it has been since the mammal was born. Another definition of "phenotype" is "the appearance or other characteristics of an organism, resulting from the interaction of its genetic constitution with the environment." "Age" does not result from any interaction of the mammal's genetic complement with the environment. Age is a number indicating time since birth.

In the present set of claims, the donor nucleus has to be nonembryonic, which means the nucleus can be from a fetus. Richardson teaches that at 90 days post-conception, the bovine is a fetus. Thus, the clone and the nuclear donor can be only 90 days apart in age. At any stage of life, one would be hard pressed to observe a difference between the clone and the nuclear donor. There would be no "observable physical or biochemical traits" that are different between the clone and the nuclear donor, and age would not be a phenotype. In addition, while a newborn mammal may not look like an adult mammal, a 13 year-old mammal and a 14 year-old mammal look alike to the extent that they are indistinguishable. If one compares the new born with a noticeably older nuclear donor, then the clone will look younger, but all one has to do is wait until the "younger" clone looks like the donor, then age as an observable phenotype disappears.

Art Unit: 1632

In addition, "age" and "clone" are not structural phenotypes. Neither is expressed in the 3-dimensional structure of the mammal. A structural or physical phenotype is an expression of the genotype such as brown hair, blue eyes and the like. There is no gene or group of genes that determine age. The expression of genes can be characteristic of an individual's developmental stage such as juvenile or adult, but these genes would not be considered to be an indication of the number of years the individual has been born. Neither "age" nor "clone" are encoded by the mammal's genome, and thus are not phenotypes.

Further, a time-delayed copy is still a copy. A copy of a mammal known in the art at the time of is not patentable because the original mammal would constitute art against the copy. As an example, amylase known in the art to have been purified from salivary glands would constitute prior art against amylase produced by bench-top synthesis. Unless the amylase made by bench-top synthesis had a new property, it would be found anticipated by amylase purified from salivary glands. In the presence case, the known mammal anticipates the copy. Thus, the bovines cited anticipate the claimed invention. It does not matter the means for obtaining the copy that is by sexual or nonsexual reproduction, as long as the copy and the clone are regarded as the same. Applicant has stated on the record that they are the same.

The claims do not state any particular age difference between the clone and the donor, or any particular ages of the clone and the donor. As the claims encompass mammals that are only 90 days apart in age, the art would stand even if one were to agree that a 1-day old calf is phenotypically different from a 5-year old calf. The specification, however, does not discuss age as a phenotype or the relative ages of the clones and the donors.

Art Unit: 1632

Thus, the rejections are maintained because no patentable distinction can be discerned between the claimed clones and the mammals known in the art at the time of filing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

November 23, 2004